

**REMARKS**

Claims 1-16, 20-30, 32-38 and 40-42 remain pending in the application. Based on the following remarks, reconsideration and allowance of the application is respectfully requested.

**Double patenting rejection**

Claims 1-5, 10, 12, 15, 16, 20, 30, 32, 33 and 40 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Application Ser. No. 10/694,927 ('927 application) in view of Martinez (U.S. Pub. No. 2004/0098028). Applicant respectfully traverses this rejection, because the '927 application has been abandoned since 2/19/08. As such, Applicant respectfully requests the withdrawal of the provisional double patenting rejections.

**Claim Rejections - 35 U.S.C. §103**

Claims 1-8, 14-16, 20, 21, 24, 27, 30, 34-36 and 40-42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,193,728 ("Ken") in view of U.S. Patent No. 5,669,931 ("Kupiecki") in further view of U.S. Patent No. 7,066,904 ("Rosenthal"). According to the Office Action, Ken discloses the device as claimed, except that the stretch resistance member contracts, and allegedly it would have been obvious to incorporate a hydrogel for carrying a drug within the lumen of an occlusive coil, having the hydrogel as a coating that contract over the stretch-resistance element of Ken, in view of Kupiecki and Rosenthal. Applicant respectfully disagrees and requests reconsideration and withdrawal of these rejections.

For a combination of prior art references to render a claim obvious, the resulting prior art device must meet all of the limitations of that claim (MPEP §2143). The stated reasoning in support of the conclusion that the pending claims are obvious appears contrary to the actual disclosures of the respective references being combined, since even if they could somehow be combined, such combination would not achieve the claimed invention.

Independent claims 1, 30, and 40 each recite an active element (claims 1 and 40) or hydrogel member (claim 30) having a pre-deployment configuration carried entirely within the lumen defined by a vaso-occlusive member, wherein the active element or hydrogel **contracts**, without the application of mechanical force, to a deployed configuration that **causes the occlusive member to substantially retain its shape** (claims 1 and 30) **or to stiffen** (claim 40) **when deployed** in a body cavity (claims 1 and 40) or vasculature (claims 30).

Ken discloses a vaso-occlusive coil with a stretch resistant member disposed within its lumen, which according to the office action (page 4) the stretch resistance member (108) of Ken is considered by the Examiner as the active element on the present claims. The stretch resistance member of Ken primary purpose is to prevent stretching of the vaso-occlusive coil by having the stiffness necessary to hold the coil in place. However, Ken does not disclose that the stretch resistance member contracts, as acknowledged by the Examiner, to thereby **cause** the occlusive member to substantially **retain its shape when deployed** in a body cavity. In particular, the stretch resistance member of Ken does not contract with or without application of mechanical force. Neither Kupiecki nor Rosenthal supply these missing features of the claims.

Kupiecki discloses a flexible occlusive implant/coil having a proximal portion that fold upon itself (e.g. ball-like mass) and maintain such configuration without resistance, when deployed. The coil interior may be filled with drugs material and have the ends partially sealed for slow drug released from the coil. (Col. 2, lines 47-64, Col. 6, lines 11-17). Rosenthal discloses a balloon catheter comprising a hydrogel coating on its outer surface; the hydrogel carries a drug that is released from the hydrogel in a body when the hydrogel is exposed to a triggering agent, which makes the hydrogel to contract and the drug to be squeezed out of the contracted hydrogel. (Col 1, line 47 to Col 2 line 57, Col 6, lines 55-64, Fig 4).

Even if a person skill in the art were to combine the teachings of Ken, in view of Kupiecki or Rosenthal, the resulting device would include a stretch resistance member of Ken having a hydrogel coating, where the coating may contract to squeeze out drugs when exposed to a triggering agent. However, such combination will not produce a device having a stretch resistance member (active element) that contracts without the application of mechanical force, to cause the occlusive member to substantially retain its shape.

The materials used in constructing the stretch resistance member of Ken are metals or their alloys *“tailored to accomplish and appropriate blend of flexibility and stiffness”* (Ken, Col 4, lines 17-28) which prevents “stretching of the coil during movement of that coil” (Ken (57) lines 10-11). The stretch resistant member of Ken would be able to bend with the bending of the occlusive member and would be able to maintain its stiffness after the occlusive member it is positioned in the body, but it is factually incorrect and not consistent with the disclosure of Ken that a stretch resistance member would

contract if a hydrogel coating is incorporated onto or into the stretch resistance member. The hydrogel coating may contract but in no event it would contract the active element (stretch resistance member), and, instead, it is the stiffness of the stretch resistance member that retains the shape of the coil after delivery.

The Examiner further states that *“the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape”* (Office action, page 5). Whether or not the Examiner’s interpretation of the independent claims is correct, contraction of the stretch resistance member of Ken is not possible, even if combined with the drugs or hydrogel of Kupiecki and Rosenthal. A contracted coating over the stretch resistance member will cause the release of drugs but will not cause the coil to substantially retain its shape, as required in independent claims 1, 30 and 40.

For at least these reasons, Applicants respectfully submit that independent claims 1, 30 and 40 are patentable over Ken in view of Kupiecki and Rosenthal. Dependent claims 2-8, 14-16, 20, 21, 24, 27, 34-36, 41 and 42 incorporate all of the limitations of their respective independent claims, which are believed to be patentable for the same reasons set forth above. Applicants respectfully request withdrawal of the §103 rejection of these claims.

Claims 9-13, 22-26, 28, 29 and 36-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view Kupiecki, in view of Rosenthal and in still further view of US Publication No. 2001/0046518 (“Sawhney”). Applicant respectfully

traverses this rejection, since the combination of the above-identified four separate references does not disclose or suggest the elements required by these claims.

Sawhney discloses methods for hydrating (expanding) hydrogel in situ, which releases therapeutic agents to a body to promote sealing or augmentation of tissue or vessels (Paragraphs 22, 26, 104). Sawhney also discloses different types of hydrogels. As discussed above, however, a combination of Ken in view of Kupiecki and Rosenthal will not produce an occlusive device with an active element that contract to cause the occlusive member to substantially retain its shape when deployed in a body cavity or vasculature site. Modifying Ken in view of Kupiecki and Rosenthal, in view of Sawhney will still not render such device, since further modifying the device in view of Sawhney would produce expansion, not contraction, of the hydrogel (regardless of the type) in-situ.

Claims 9-13, 22-26, 28 and 29 incorporate all of the elements and limitations of independent claim 1, and claims 36-38 incorporate all of the elements and limitations of independent claim 32 (rejected under double patenting rejection), and therefore are allowable for at least the same reasons. Applicant respectfully requests withdrawal of the §103 rejections over the respective combinations of Ken, Kupiecki, Rosenthal and Sawhney.

**CONCLUSION**

In view of the foregoing remarks, it is believed that all currently pending claims are in condition for allowance. Applicant respectfully requests a notice of allowance. If there are any questions concerning this amendment and response, please contact the undersigned at the number below.

Respectfully submitted,  
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